#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Hodge, et al. Atty. Ref.: 18034-PCTUS

Patent No.: 7,514,555

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Appl. No.: 10/531,618 Group Art Unit: 1614

Filed: April 14, 2005 Examiner: Weddington, K. E.

Conf. No.: 8180 Customer No.: 31976

Title: COMPOUNDS FOR THE TREATMENT OF METABOLIC

**DISORDERS** 

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June 3, 2009

Commissioner for Patents P.O. Box 1450
Alexandria VA 22313 145

Alexandria, VA 22313-1450

Attn.: Office of Patent Legal Administration

Sir:

# REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(d)

This Request for Reconsideration of Patent Term Adjustment is being filed within two (2) months of the issue date of the above-identified patent. And this Request concerns issues that arose after payment of the issue fee. Therefore this Request is timely (37 CFR 1.705(d)). The fee set forth in 37 CFR 1.18(e) is enclosed.

Patentees respectfully request reconsideration of the Patent Term Adjustment for this patent. The Office determined that the patent is entitled to a term adjustment of **82 days**. The correct term adjustment is not less than **241 days**.

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# **ISSUE PRESENTED**

This patent is entitled to a term extension equal to the sum of: (A) Office delays in taking certain actions; and (B) the amount of time, in excess of three years from the filing date, that it took for the patent to be issued. The Office erred in extending the term only for (B).

### LAW OF PATENT TERM ADJUSTMENT

The term of a patent is extended for the number of days that issuance of the patent was delayed by failures of the Office to promptly take certain actions (35 U.S.C. § 154(b)(1)(A)) ("A delays"). And the term of a patent is extended for the number of days that the Office failed to issue a patent by the three-year anniversary of the date that the application for patent was filed (35 U.S.C. § 154(b)(1)(B)) ("B delay"). The Patent Term Adjustment is calculated by adding the "A delays" plus the "B delay," except to the extent that the periods of delay overlap (35 U.S.C. § 154(b)(2)(A)). "'B delay' begins when the PTO has failed to issue a patent within three years, not before." *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 142 (D.D.C. 2008). Therefore a "B delay" does not overlap with "A delays" that occurred during the first three years that a patent application was pending. *Id.* at 141.

In this case the Office has calculated the Patent Term Adjustment in accordance with its earlier, contrary "position that . . . the entire period during which the application was pending before the Office . . . and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay 'overlap' under 35 U.S.C. 154(b)(2)(A)." 69 Fed. Reg. 34283 (June 21, 2004). The Office's position is "inconsistent with law" (*See* 35 U.S.C. § 2(b)(2)) as interpreted by the court in *Wyeth*.

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# "A DELAYS"

The period of adjustment under 37 CFR 1.702(a) is the sum of the following periods:

- (1) "The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application . . . fulfilled the requirements of 35 U.S.C. 371 and ending on the date of mailing of . . . an action under 35 U.S.C. 132. . . . " (37 CFR 1.703(a)(1)). The application entered national phase on April 14, 2005 and the first Office Action was mailed on November 7, 2006. The day after the date that is fourteen months after the application entered national phase was June 15, 2006. And the delay was **146 days**, which is the number of days in the period from June 15 to November 7, 2006.
- (2) "The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply under § 1.111 was filed and ending on the date of mailing of . . . an action under 35 U.S.C. 132. . . ." (37 CFR 1.703(a)(2)). Patentees filed a reply on May 7, 2007 and the next Office Action was mailed on September 20, 2007. The day after the date that is four months after the reply was September 8, 2007. And the delay was 13 days, which is the number of days in the period from September 8 to September 20, 2007.

The total "A delay" was 159 days, which is the sum of 146 days plus 13 days.

#### "B DELAY"

"The period of adjustment under [37 CFR] § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which . . . the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued. . . ." (37 CFR 1.703(b)).

The patent application commenced national stage on April 14, 2005 and the patent issued on April 7, 2009. The day after the date that is three years after commencement of national stage was April 15, 2008. And the total "B delay" was **358 days**, which is the number of days in the period from April 15, 2008 to April 7, 2009.

## CALCULATION OF PATENT TERM ADJUSTMENT

All of the "A delay" occurred during the first three years that the patent application was pending. Accordingly, under *Wyeth*, there is no overlap between the "A delays" and the "B delay" in this case. Therefore, the period of adjustment due to Office delays is **517 days**, which is the sum of the 159 days of "A delays" and the 358 days of "B delay."

The period of Office delay is "reduced by . . . the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution" (37 CFR 1.704), which the Office determined to be **276 days**. Thus the total Patent Term Adjustment is not less than **241 days**, which is 517 days less 276 days.

The patent is not subject to a terminal disclaimer. 37 CFR 1.703(g).

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No fee, other than the fee under 37 CFR 1.18(e), is believed to be necessary in connection with the filing of this paper. If any additional fee is required, the Director is authorized to charge the additional fee to Deposit Account No. 50-1677.

Respectfully submitted,

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